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| MEDICINELODGE INC. 180 SOUTH 600 WEST LOGAN, UT 84321 | | | EXAMINER BLATT, ERIC D | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,746

Applicant(s)

SINNOTT ET AL.

Examiner

Eric Blatt

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 21-54 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-24 and 27-28 rejected under 35 U.S.C. 102(b) as being anticipated by Borzone et al. (US 5,814,070).

Regarding claims 21-24, Borzone discloses a disuse retention system (Figure 6) comprising a suture anchor 34 wherein the suture anchor comprises:

- an elongated body having a proximal end and an opposing distal end displaced from the proximal end along a longitudinal axis, wherein a first suture port 38 extends through at least a portion of the body; and
- a helical thread wound about and outwardly projecting from the elongated body (Figure 6);
- at least a first portion (portion of port 38 nearest the proximal face) of the first suture port extends substantially parallel to the longitudinal axis;
- the first suture port is spaced apart from the longitudinal axis so as to not intersect the longitudinal axis;
- the elongated body is formed as a single, unitary piece;
- the first suture port extends distally of a proximal end of the helical thread;

- the first suture port intersects the helical thread; and
- at least a second portion (portion of port 38 extending around the anchor) of the first suture port extends nonparallel to the longitudinal axis.

Regarding claims 27-28, Borzone discloses that the system further comprises:

- at least one suture positionable through at least the first suture port (Column 4, Lines 1-25); and
- a tool 50 configured to interface with the suture anchor to facilitate driving the suture anchor into bone (Figure 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25, 29-32, 34-36, 45-51, and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borzone et al. (US 5,814,070) in view of Wenstrom, Jr. et al. (US 6,045,573).

Regarding claims 25, 35, and 36, Borzone discloses all elements of claims 25, 35, and 36 as previously discussed except that a second suture port extends through a portion of the body, wherein the first and second suture ports are arranged symmetrically about the longitudinal axis. Wenstrom discloses that it was known to

provide a second suture port, such that the first and second suture ports are arranged symmetrically about the longitudinal axis. (Figure 1, Column 2) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Borzone by providing a second suture port, similar to the first port, such that the first and second suture ports are arranged symmetrically about the longitudinal axis for purposes such as allowing the suture anchor to anchor more than one thread as taught by Wenstrom. It also would have been obvious to one of ordinary skill in the art at the time of the invention to provide a second suture portion for purposes such as allowing the device to achieve more soft tissue fixation as taught by Wenstrom. (Column 2, Lines 1-20) The device shown in Figure 6 of Borzone has a single port comprising two holes into the proximal face on opposite sides with and a transverse portion wrapping half-way around the anchor to connect the two holes. Upon modifying the device, the device would have two ports, each comprising two holes into the proximal face and a transverse portion connecting them.

Regarding claims 29-35, the modified device holds first and second suture portions wherein the first and second suture portions are separate pieces from each other. At least a portion of the first and second suture ports extend distally from the proximal end of the helical thread, and the first and second suture ports are displaced from the longitudinal axis. (Figure 6) At least a portion of each of the first and second suture ports extends nonparallel to the longitudinal axis.

Regarding claims 45, 48, 51, 53, and 54, the first and second suture ports of the modified device are configured to receive an intermediate suture portion such that the

first and second suture ports cooperate to provide four parallel suture lengths extending proximally of the proximal end. A first portion of each of the first and second suture ports extends parallel to the longitudinal axis, and a second portion extends nonparallel to the longitudinal axis.

Regarding claims 46 and 47, the first suture port intersects an exterior sidewall of the elongated body so as to communicate with a first opening of the exterior side wall, and the second suture port intersects the exterior sidewall so as to communicate with a second opening of the exterior sidewall. The first and second openings intersect the helical thread. It should be noted that the ports shown in the device of Figure 6 of Borzone are grooves cut into the exterior of the device and are not completely surrounded by the material of the device. The transverse portions of the ports are cut into the exterior side walls to allow an opening for the suture to pass around the device. Thus, these portions are considered openings in the exterior side walls.

Regarding claims 49 and 50, as previously stated, the modified device of Borzone has two suture ports, each comprising two holes into the proximal end face and a transverse portion connecting them. Suture may be threaded through each hole. Reinterpreting each hole to be a suture port, the anchor comprises first, second, third, and fourth suture ports, each intersecting the proximal end face so as to communicate with first, second, third, and fourth openings of the proximal end face respectively. The first suture port adjoins the third suture port via the first transverse portion between them so as to facilitate positioning a first intermediate suture portion within the first and third suture ports. The second suture port adjoins the fourth suture port via the second

transverse portion so as to facilitate positioning a second intermediate suture portion within the second and fourth suture ports.

Claims 26, 37-40, and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borzone et al. (US 5,814,070) in view of Winters et al. (US 6,569,186).

Regarding claim 26, Borzone discloses all elements of claim 26 except that a bore extends full through the body along the longitudinal axis, wherein the first suture port is positioned such that the first suture port is not in communication with the bore. The driving tool of Borzone interfaces with the outside of the proximal end of the suture anchor. Winters discloses an alternate system for driving a suture anchor wherein the suture anchor comprises a bore having a substantially hexagonal drive feature, wherein the bore passes through the body of the anchor along the longitudinal axis, and a driving tool that interfaces with the interior of said bore. (Figures 5, 6B, and 9-10) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Borzone by providing the driving system disclosed in Winters since this system was a known alternative and its substitution would have produced expected results. As taught by Winters, the bore of the modified device is not in communication with the suture port.

Regarding claims 37-40 and 42-44, the modified device comprises a bore extending fully through the body along the longitudinal axis. The first suture port extends distally of a proximal end of the helical thread and intersects the helical thread.

A second portion of the first suture port extends nonparallel to the longitudinal axis. There is a tool configured to interface with the suture anchor to facilitate driving the suture anchor into bone.

Claims 33, 41, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borzone et al. (US 5,814,070) in view of Wenstrom, Jr. et al. (US 6,045,573) as applied to claims 25, 29-32, 34-36, 45-51, and 53-54 above, and further in view of Winters et al. (US 6,569,186).

Regarding claim 33 claims 33 are disclosed by Borzone in view of Wenstrom as previously discussed except that a bore extends fully through the body along the longitudinal axis, wherein the first and second suture ports are positioned such that the first and second suture ports are not in communication with the bore. The driving tool of Borzone interfaces with the outside of the proximal end of the suture anchor. Winters discloses an alternate system for driving a suture anchor wherein the suture anchor comprises a bore having a substantially hexagonal drive feature, wherein the bore passes through the body of the anchor along the longitudinal axis, and a driving tool that interfaces with the interior of said bore. (Figures 5, 6B, and 9-10) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Borzone by providing the driving system disclosed in Winters since this system was a known alternative and its substitution would have produced expected results. As taught by Winters, the bore of the modified device is not in communication with the suture port.

Regarding claim 41, the bore of the modified device is shaped to receive a distal end of a driver to facilitate transmission of torque from the driver to the suture anchor, and the first and second suture ports are symmetrically arranged about the longitudinal axis.

Regarding claim 52, the modified suture anchor comprises a substantially hexagonal drive feature positioned to receive torque from a tool to facilitate driving the suture anchor into bone.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- DiPoto; Gene P. et al. (US 5258016): Suture anchor and driver assembly
- Jenkins, Jr.; Joseph R. (US 5571139): Bidirectional suture anchor
- Grafton; R. Donald et al. (US 6319270): Headed bioabsorbable tissue anchor
- Anderson; David W. et al. (US 6436124): Suture anchor
- Burkhart; Stephen S. (US 6540750): Suture anchor reel device, kit and method
- Martello; Jeannette (US 7163540): Soft tissue securing anchor
- Jensen; David G. et al. (US 7235079): Composite bone fasteners
- Graf, Ben K. et al. (US 2002/0042615): Graft anchor
- Overaker, David W. (US 2002/0120281): Scaffold fixation device for use in articular cartilage repair

- Martinek, Jonathan (US 2002/0147463): Suture screw
- Burkhardt, Stephen S. (US 2004/0172062): Suture anchor reel device, kit and method

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is 571-272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER